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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,587	03/29/2004	Daniele Pressato	2039-0124PUS2	2626

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BIRCH STEWART KOLASCH & BIRCH  
PO BOX 747  
FALLS CHURCH, VA 22040-0747

EXAMINER
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MAIER, LEIGH C

ART UNIT	PAPER NUMBER
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1623

NOTIFICATION DATE	DELIVERY MODE
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04/09/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/812,587	<b>Applicant(s)</b> PRESSATO ET AL.	
	<b>Examiner</b> Leigh C. Maier	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11 and 16-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11 and 16-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

Claims 12-15 have been canceled. Claims 11, 17, 19, 20 and 26 have been amended. Claims 27-30 are newly submitted. Claims 11 and 16-30 are pending. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any rejection or objection not expressly repeated has been withdrawn.

### ***Allowable Subject Matter***

Claims 11 and 16-30 are deemed to be free of the art but are subject to obvious-type double patenting rejections, as set forth below.

Huang et al (US 5,532,221) teaches the use of crosslinked HA for the prevention of surgical adhesions, as set forth in previous Office actions. Johns et al (Fertil. Steril., 1997) teaches that a crosslinked hyaluronic acid product having only 5% crosslinking is not effective at inhibiting surgical adhesions. See page 40, 1<sup>st</sup> full paragraph. Therefore, one of ordinary skill would not have a reasonable expectation of success in using the Della Valle product having 5% crosslinking.

As noted previously the claims describe the viscosity of the product used in the units of “Pa\*sec<sup>-1</sup>” which does not appear to be a standard unit used in the art to measure viscosity. However, upon further consideration of the art, the units as written would be recognized by one of ordinary skill as the more typical “Pa\*sec.” The use of this unit does not change the scope of what would be understood by one of ordinary skill.

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With respect to the claims reciting viscosity, the claims recite “wherein said cross-linked derivative has a viscosity of [viscosity value].” These claims are construed as “wherein said *biomaterial comprising the* cross-linked derivative has a viscosity of [viscosity value].”

Otherwise, the viscosity limitation would be superfluous because any crosslinked hyaluronic acid having the recited molecular weight in the absence of any diluent would have a much greater viscosity. This is consistent with the specification. See, for example, paragraphs [0061] and [0465]. Applicant may consider amending to clarify this.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11 and 16-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-15 and 6 of U.S. Patent No. 6,723,709 in view of Della Valle (EP 341745).

The claims of '709 are drawn to a method of preventing surgical adhesions by application of a biomaterial comprising 4.5 to 5% autocrosslinked hyaluronic acid, along with other synthetic polymers, in a wide variety of surgical procedures. The claims do not recite any particular molecular weight for the hyaluronic acid or a viscosity for the biomaterial. Further claims recite a product for this method in the form of a gel, membrane, etc. and further comprising biologically active agents, such as anti-inflammatories, etc.

Della Valle teaches a crosslinked product, as discussed previously. The reference suggests the preparation of these products using a hyaluronic acid having average molecular weight of about 250,000 to about 350,000.

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare the crosslinked product recited in the claims with a hyaluronic acid having a molecular weight as suggested by Della Valle with a reasonable expectation of success. With respect to the viscosity, it would be within the scope of the artisan to optimize the viscosity through routine experimentation.

Claims 11 and 16-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11, 12, 15, 16, 21 and 22 of U.S. Patent No. 7,202,230 in view of Della Valle (EP 341745).

The claims of '230 are drawn to a surgical method comprising the application of a biomaterial comprising 3-10% autocrosslinked hyaluronic acid and synthetic polymers, such as PTFE, and a pharmacologically active substance such as anti-inflammatory agents, wherein the biomaterials may be in the form of films, gels, etc. The claims do not teach any particular molecular weight or viscosity or a crosslinking range as narrow as the instant claims. The claims do not recite inhibition of surgical adhesions.

Della Valle teaches as set forth above.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare the crosslinked product recited in the claims with a hyaluronic acid having a molecular weight as suggested by Della Valle with a reasonable expectation of success. With respect to the viscosity and percent crosslinking, it would be within the scope of the artisan to optimize these variables for the claimed surgical procedure through routine experimentation. It would appear that the optimized range for this procedure would overlap with

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the optimized range in the instant claims. In carrying out the procedure as claimed in '230, the inhibition of surgical adhesions would inherently be achieved.

***Examiner's hours, phone & fax numbers***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov> Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

/Leigh C. Maier/  
Primary Examiner, Art Unit 1623  
March 28, 2008